

AMENDMENTS TO THE SPECIFICATION

Replace the third full paragraph on page 5 of the substitute specification filed on June 26, 2003 with the following:

It is therefore an object of the invention to provide a new and improved stable isotopic identification, and a method of identifying ~~batched~~ products utilizing stable isotopic identification.

Replace the fourth full paragraph on page 5 of the substitute specification filed on June 26, 2003 with the following:

It is also an object of the invention to provide a new and improved stable isotopic identification, and a method for identifying ~~batched~~ products utilizing the same which is fully operational utilizing naturally occurring variations in isotopic abundance, thus eliminating costly taggants.

Replace the first full paragraph on page 6 of the substitute specification on June 26, 2003 with the following:

It is also an object of the invention to provide a new and improved stable isotopic identification utilizing the intrinsic or ambient variability and the stable isotopic composition or ratios of the product (not artificially altered or "tagged") thereby eliminating the need for relatively expensive taggants and the resultant dilution or impurity of the product, and a method utilizing such isotopic concentrations or ratios in a machine readable form for identifying ~~batched~~ products and tracking ~~batched~~ products through manufacturing, marketing and use of a product, and readily indexing product information to the product.

Replace the second full paragraph on page 6 of the substitute specification filed on June 26, 2003 with the following:

It is also an object of the invention to provide a new and improved stable isotopic identification derived from stable isotopic compositions or ratios of the common light elements in batched products, and a method of identifying batched products and indexing product information to the product utilizing the same.

Replace the fifth full paragraph beginning on page 6 of the substitute specification filed on June 26, 2003 with the following:

In the broader aspects of the invention there is provided a stable isotopic identification comprising a mathematical or numerical array of concentrations of isotopes found in a batched product, said mathematical or numerical array being presented in a machine readable form and comparable to analytical results whereby the product can be distinguished from other similar products, said machine readable form also being indexed through stored product information. The stored product information may be displayed when desired. By the stable isotopic identification of the invention, a product may be securely traced through manufacturing of a product, marketing of a product and the use of a product.

Replace the first full paragraph on page 7 of the substitute specification filed on June 26, 2003 with the following:

A method of identifying batched products is also provided utilizing the stable isotopic identification including the steps of analyzing a product for the concentration of isotopes, arranging the concentrations of the isotopes in a mathematical or numerical array, formulating the mathematical or numerical array in a machine readable form,

assembling product information, and indexing the product information to the machine readable form of the mathematical or numerical array, maintaining both the indexing and the product information, and when desired measuring the isotopic concentration of a comparable substance, comparing the mathematical or numerical arrays, and accessing stored product information through the indexing of the same to product information, whereby a product may be traced through manufacturing, the marketplace and use, identified, and indexed to product information.

Replace the second full paragraph beginning on page 7 of the substitute specification filed on June 26, 2003 with the following:

The present invention provides a stable isotopic identification of batched products and a method for utilizing such isotopic concentrations (which in a specific embodiment may be expressed in isotopic ratios) in a machine readable form for identifying batched products and tracking batched products through manufacturing, marketing and use of a batched product, and readily indexing product information to the batched product, especially with pharmaceutical phases, such as active pharmaceutical ingredients (APIs), drug products, the excipients of drug products and/or impurities of drug products utilizing concentrations of naturally occurring stable isotopes, and formulating a stable isotopic identifications therefrom. The present invention also provides a unique method for utilizing the stable isotopic identification of the invention and identifying batched products later in the manufacturing or the marketing or the use or misuse of the product and referencing the same to detail product information, serial numbers, or the like for identifying fraudulent products or "knock-offs" throughout the

chemical, petroleum, pharmaceutical, biomedical, foodstuff, environmental, paint, explosive-ammunition and combustible fuel industries.

Delete the first full paragraph beginning on page 8 of the substitute specification filed on June 26, 2003:

The term "batched product" is used herein to include products manufactured in the batch mode, in contrast to continuously manufactured products. The term "batched product" includes pharmaceutical ingredients, excipients of drug products, impurities in drug products, raw materials in drug products, additives to combustible fuels, batched combustible fuels, batched natural occurring products, explosive products, ammunition, gun powder, batched crude oil, batched petroleum distillates, hazardous waste, paper, ink, tire materials, paints and other coatings and other batched manufactured products including continuously manufactured products or naturally occurring products which are subsequently batched. All "batched products" within this definition are homogenous to the extent that multiple samples from the batched products will have the same composition as determined within the error of analysis and sampling. Thus, while the term "batched product" as that term is used in this application may refer to a homogenous sample of a continuously produced product or a naturally occurring product, the "batched product" will only relate to the continuously manufactured product or the naturally occurring product from which it came within the error of sampling. Thus, the sample of a batched product which is traced by the method of the invention to the batched product can only be traced to its origins within the error in the sampling.

Replace the first full paragraph beginning on page 10 of the substitute specification filed on June 26, 2003 with the following:

Further, isotopic concentrations provide stable isotopic identifications which are highly specific. Elements which have more than one stable isotope are numerous. Of the 83 known non-radioactive elements known to exist on earth, 62 have more than one stable isotope, and 40 have more than two stable isotopes. The element tin (Sn) has the largest number of stable isotopes for any single element. Among the 40 elements having more than two stable isotopes, there are a total of 224 stable isotopes. Although a few of the 220 224 stable isotopes are slightly radioactive, they have very long lives and are present in many naturally occurring elements. Thus, as will be seen, the stable isotopic identifications of the invention are numerous and provide a ready and available means by which any product (including all pharmaceutical phases APIs, drug products, excipients of drug products and/or impurities of drug products) may be readily identified.